

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Display Date	5-2-00
Publication Date	5-3-00
Certifier	M. Beep

Food and Drug Administration

21 CFR Part 510

New Animal Drugs; Change of Sponsor's Name and Address

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor's name and address for Global Pharmaceutical Corp.

DATES: This rule is effective *[insert date of publication in the Federal Register]*.

FOR FURTHER INFORMATION CONTACT: Thomas J. McKay, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0213.

SUPPLEMENTARY INFORMATION: Global Pharmaceutical Corp., Castor and Kensington Aves., Philadelphia, PA 19124, has informed FDA of a change of sponsor's name and address to IMPAX Laboratories, Inc., 30831 Huntwood Ave., Hayward, CA 94544. Accordingly, the agency is amending the regulations in 21 CFR 510.600(c)(1) and (c)(2) to reflect the change of sponsor's name and address.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects in 21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 510 is amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

§ 510.600 [Amended]

2. Section 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications* is amended in the table in paragraph (c)(1) by removing the entry for “Global Pharmaceutical Corp.” and by alphabetically adding an entry for “IMPAX Laboratories, Inc., 30831 Huntwood Ave., Hayward, CA 94544”; and in the table in paragraph (c)(2) in the entry

for "000115" by removing the sponsor^{is} name and address and by adding in ^{their}its place "IMPAX
Laboratories, Inc., 30831 Huntwood Ave., Hayward, CA 94544. LDC

Dated: 4/24/00

April 24, 2000

Claire M. Lathers

Claire M. Lathers
Director
Office of New Animal Drug Evaluation
Center for Veterinary Medicine

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

BILLING CODE 4160-01-F

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

Michael W. Bell